

CLAIMS:

1. A method of detecting in a mammal the onset, or predisposition to the onset, of a condition characterised by modulation of the level or bioactivity of activin β_C , which level is modulated relative to normal levels, said method comprising screening for the level of activin β_C protein and/or gene expression in a biological sample derived from said mammal.
2. A method of monitoring for the onset or progression of a condition characterised by modulation of the level or bioactivity of activin β_C in a mammal, which level is modulated relative to normal levels, said method comprising screening for the level of activin β_C protein and/or gene expression in a biological sample derived from said mammal.
3. The method according to claim 1 or 2 wherein said activin β_C subunit is in monomeric form.
4. The method according to claim 1 or 2 wherein said activin β_C subunit is in dimeric form.
5. The method according to claim 4 wherein said activin β_C dimer is one or more of activin AC ($\beta_A-\beta_C$), activin BC ($\beta_B-\beta_C$), activin C ($\beta_C-\beta_C$), activin CD ($\beta_C-\beta_D$) or activin CE ($\beta_C-\beta_E$).
6. The method according to any one of claims 1-5 wherein said condition is a condition of the pancreas, brain and neural tissue, adrenal gland, thyroid gland, stomach, colon, urinary bladder, endometrium, breast, lymph node, skin, salivary gland, bone, nasal cavity, duodenum, gallbladder, uterine cervix, thymus, fallopian tube, uterus, tonsil, spleen, appendix, seminal vesicle, larynx, tongue, small intestine, rectum, oesophagus, myometrium and soft tissue.

7. The method according to claim 6 wherein said condition is a malignant neoplasia.
8. The method according to claim 7 wherein said malignant neoplasia is a malignant neoplasia of the pancreas, brain and neural tissue, adrenal gland, thyroid gland, stomach, colon, bladder, endometrium, breast, lymph node, skin, salivary Gland, bone, nasal cavity, duodenum, gallbladder, cervix, thymus, larynx, tongue, small intestine, rectum or oesophagus, seminal vesicle cancer, brain cancer, splenic cancer or soft tissue cancer.
9. The method according to claim 7 wherein said condition is a non-malignant neoplasia.
10. The method according to claim 9 wherein said non-malignant neoplasia is a neoplasia of the fallopian tube, uterus, tonsil, spleen, appendix, seminal vesicle, myometrium or soft tissue.
11. The method according to any one of claims 6-10 wherein said modulation is an increase in the level or bioactivity of activin β_C subunit.
12. The method according to any one of claims 6-10 wherein said modulation is a decrease in the level or bioactivity of activin β_C subunit.
13. The method according to claim 11 or 12 wherein the biological sample is selected from the group including serum, tissue extracts, body fluids, cell culture medium, extracellular medium, supernatants, biopsy specimens or resected tissue.
14. The method according to any one of claims 1-13 wherein the screening assay is directed to detecting the activin β_C subunit and is performed utilising an antibody directed to activin β_C subunit.

- 93 -

15. The method according to any one of claims 1-13 wherein said screening assay is directed to detecting activin β_C dimers and is performed utilising an antibody directed to the activin β_C subunit and one or more antibodies directed to one or more of the activin β_A , β_B , β_C , β_D or β_E subunits.
16. The method according to claim 15 wherein said activin β_C dimer is one or more of activin AC (β_A - β_C), activin BC (β_B - β_C), activin C (β_C - β_C), activin DC (β_D - β_C) or activin EC (β_C - β_E).
17. The method according to any one of claims 14-16 wherein said antibody recognises an epitope of activin β_C comprising the amino acid sequence:
VPTARRPLSLLYYDRDSNIVKTDIPDMVVEAC (SEQ ID NO:1) or equivalent thereof.
18. A method of detecting the onset, predisposition to the onset, or monitoring for the onset or progression, of a condition characterised by modulation of the level of activin β_C in a mammal, which level is modulated relative to normal levels, said method comprising:
 - (a) contacting a first antibody that recognises an epitope of a first activin β subunit with a biological sample derived from said mammal;
 - (b) allowing the first antibody to bind to said first activin β subunit in said sample;
 - (c) washing said sample to substantially remove unbound material;
 - (d) contacting said sample with a second antibody that recognises an epitope of a second activin β subunit, wherein the second antibody is tagged with a labelling agent; and

- (e) detecting the labelling agent to identify an activin β_C subunit dimer in said sample, wherein the first or second antibody recognises an epitope of an activin β_C subunit.
- 19. The method according to claim 18 wherein said activin β_C dimer is one or more of activin AC (β_A - β_C), activin BC (β_B - β_C), activin C (β_C - β_C), activin CD (β_C - β_D) or activin CE (β_C - β_E).
- 20. The method according to any one of claims 18-19 wherein said condition is a condition of the pancreas, brain and neural tissue, adrenal gland, thyroid gland, stomach, colon, urinary bladder, endometrium, breast, lymph node, skin, salivary gland, bone, nasal cavity, duodenum, gallbladder, uterine cervix, thymus, fallopian tube, uterus, tonsil, spleen, appendix, seminal vesicle, larynx, tongue, small intestine, rectum, oesophagus, myometrium and soft tissue.
- 21. The method according to claim 20 wherein said condition is a malignant neoplasm.
- 22. The method according to claim 21 wherein said malignant neoplasm is a malignant neoplasm of the pancreas, brain and neural tissue, adrenal gland, thyroid gland, stomach, colon, bladder, endometrium, breast, lymph node, skin, salivary Gland, bone, nasal cavity, duodenum, gallbaldder, cervix, thymus, larynx, tongue, small intestine, rectum or oesophagus, seminal vesicle cancer, brain cancer, splenic cancer or soft tissue cancer.
- 23. The method according to claim 20 wherein said condition is a non-malignant neoplasm.
- 24. The method according to claim 23 wherein said non-malignant neoplasm is a neoplasm of the fallopian tube, uterus, tonsil, spleen, appendix, seminal vesicle, myometrium or soft tissue.

25. The method according to any one of claims 20-24 wherein said modulation is an increase in the level or bioactivity of activin β_C subunit.
26. The method according to any one of claims 20-24 wherein said modulation is a decrease in the level or bioactivity of activin β_C subunit.
27. The method according to claim 25 or 26 wherein the biological sample is selected from the group including serum, tissue extracts, body fluids, cell culture medium, extracellular medium, supernatants, biopsy specimens or resected tissue.
28. A method according to claim 27 further including adding a dissociating agent to the sample to remove binding proteins.
29. The method according to claim 28 wherein the dissociating agent is selected from the group including SDS, sodium deoxycholate and Tween 20.
30. A composition when used in the method of any one of claims 1-29, said composition comprising an activin β_C detection means.
31. The composition according to claim 30 wherein said composition comprises an antibody directed to an epitope of an activin β_C subunit together with a suitable diluent, excipient or carrier.
32. The composition according to claim 31 wherein said antibody recognises an epitope of activin β_C comprising the amino acid sequence:
VPTARRPLSLLYYDRDSNIVKTDIPDMVVEAC (SEQ ID NO:1) or equivalent thereof.
33. A diagnostic kit for use in detecting the onset, predisposition to the onset, or monitoring for the onset or progression of a condition characterised by modulation

of the level or bioactivity of activin β_C subunit, said kit comprising an activin β_C subunit protein and/or encoding nucleic acid detection means in a first compartment and reagents useful for facilitating detection by said detection means in a second compartment.

34. The kit according to claim 33 wherein said detection means is an antibody directed to an epitope of an activin β_C subunit together with a suitable diluent, excipient or carrier.
35. The kit according to claim 34 wherein said antibody recognises an epitope of activin β_C comprising the amino acid sequence:
VPTARRPLSLLYYDRDSNIVKTDIPDMVVEAC (SEQ ID NO:1) or equivalent thereof.
36. The kit according to any one of claims 33-35 when used in the method of any one of claims 1-29.
37. A method of modulating the abnormal growth of a cell, said method comprising modulating the level or bioactivity of activin β_C subunit.
38. The method according to claim 37 wherein said abnormal growth is a malignant neoplasm.
39. The method according to claim 38 wherein said malignant neoplasm is a malignant neoplasm of the pancreas, brain and neural tissue, adrenal gland, thyroid gland, stomach, colon, bladder, endometrium, breast, lymph node, skin, salivary gland, bone, nasal cavity, duodenum, gallbladder, cervix, thymus, larynx, tongue, small intestine, rectum or oesophagus, seminal vesicle cancer, brain cancer, splenic cancer or soft tissue cancer.

- 97 -

40. The method according to claim 37 wherein said abnormal growth is a non-malignant neoplasm.
41. The method according to claim 40 wherein said non-malignant neoplasm is a neoplasm of the fallopian tube, uterus, tonsil, spleen, appendix, seminal vesicle, myometrium or soft tissue.
42. The method according to any one of claims 37-41 wherein up-regulating activin β_C subunit levels or bioactivity to a functionally effective level induces said abnormal growth and down-regulating activin β_C subunit levels or bioactivity to a functionally ineffective level inhibits said abnormal growth.
43. The method according to claim 42 further comprising administering to said mammal an effective amount of an agent for a time and under conditions sufficient to induce a functionally ineffective level of activin β_C subunit.
44. The method according to any one of claims 37-41 wherein down-regulating activin β_C subunit levels or bioactivity to a functionally ineffective level induces said abnormal growth and up-regulating activin β_C subunit levels or bioactivity to a functionally effective level inhibits said abnormal growth.
45. The method according to claim 44 further comprising administering to said mammal an effective amount of an agent for a time and under conditions sufficient to induce a functionally effective level of activin β_C subunit.
46. A method of therapeutically and/or prophylactically treating a condition, or a predisposition to the development of a condition, characterised by an aberrant, unwanted or otherwise inappropriate level or bioactivity of activin β_C subunit in a mammal, said method comprising modulating the level of activin β_C subunit in said mammal.

47. The method according to claim 46 wherein said activin β_C subunit is in monomeric form.
48. The method according to any one of claims 46-47 wherein said condition is a condition of the pancreas, brain and neural tissue, adrenal gland, thyroid gland, stomach, colon, urinary bladder, endometrium, breast, lymph node, skin, salivary gland, bone, nasal cavity, duodenum, gallbladder, uterine cervix, thymus, fallopian tube, uterus, tonsil, spleen, appendix, seminal vesicle, larynx, tongue, small intestine, rectum, oesophagus, myometrium and soft tissue.
49. The method according to claim 48 wherein said condition is a malignant neoplasm.
50. The method according to claim 49 wherein said malignant neoplasm is a malignant neoplasm of the pancreas, brain and neural tissue, adrenal gland, thyroid gland, stomach, colon, bladder, endometrium, breast, lymph node, skin, salivary gland, bone, nasal cavity, duodenum, gallbladder, cervix, thymus, larynx, tongue, small intestine, rectum or oesophagus, seminal vesicle cancer, brain cancer, splenic cancer or soft tissue cancer.
51. The method according to claim 48 wherein said condition is a non-malignant neoplasm.
52. The method according to claim 51 wherein said non-malignant neoplasm is a neoplasm of the fallopian tube, uterus, tonsil, spleen, appendix, seminal vesicle, myometrium or soft tissue.
53. The method according to any one of claims 46-52 wherein down-regulating said activin β_C subunit level to a functionally ineffective level inhibits said abnormal cell growth.

54. The method according to claim 53 said method comprising administering an effective amount of an agent for a time and under conditions sufficient to induce a functionally ineffective level of activin β_C subunit.
55. The method according to any one of claims 46-52 wherein up-regulating said activin β_C subunit level to a functionally effective level inhibits said abnormal cell growth.
56. The method according to claim 55 said method comprising administering an effective amount of an agent for a time and under conditions sufficient to induce a functionally effective level of activin β_C subunit.
57. The method according to claim 54 wherein said agent is an antibody directed to the activin β_C subunit.
58. The method according to claim 57 wherein said antibody recognises an epitope of activin β_C comprising the amino acid sequence:
VPTARRPLSLLYYDRDSNIVKTDIPDMVVEAC (SEQ ID NO:1) or equivalent thereof.
59. Use of an agent capable of modulating the functionally effective level of activin β_C subunit in the manufacture of a medicament for the treatment of a condition characterised by an aberrant, unwanted or otherwise inappropriate level of activin β_C subunit.
60. Use according to claim 59 wherein said condition is abnormal cell growth.
61. Use according to claim 60 wherein down-regulating activin β_C subunit to a functionally ineffective level inhibits said abnormal growth.

- 100 -

62. Use according to claim 60 wherein up-regulating activin β_C subunit to a functionally effective level inhibits said abnormal growth.
63. A pharmaceutical composition comprising an agent capable of modulating the functionally effective level of activin β_C subunit together with one or more pharmaceutically acceptable carriers and/or diluents.
64. The composition of claim 63 when used in the method of any one of claims 37-58.